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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,806	12/28/2001	David P. Greene	YOR920010587US1	8447

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EXAMINER	
FLEMING, FRITZ M	
ART UNIT	**PAPER NUMBER**
2182	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/033,806	GREENE ET AL.	
	Examiner	Art Unit	
	Fritz M Fleming	2182	

-- The MAILING DATE of this communicati n appears n the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-46 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

FRITZ FLEMING
PRIMARY EXAMINER
GROUP 2100

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 28 December 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 8/29/2002 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites "the patient identifier" which does not have proper antecedent basis in either claim 34 or 32. Thus claims 34 and 35 are vague and indefinite.

Double Patenting

3. Claim 44 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 43. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-30 and 32-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Jovanov et al. (Wireless Personal Area Networks in Telemedical Environment). Jovanov is a competent reference for 102(b) as the paper, per the IEEE bibliographic data, was made public at the EMBS International Conference, 9-10 November 2000, more than 1 year prior to applicants' filing date of 12/28/01.

Per the title of the paper, a Personal Area Network (PAN) is disclosed. Wireless PAN is proposed at page 22, right column, 3rd paragraph. Again, page 23 has "2 Personal Area Networks" as a section title. A PAN is a client server network with a single personal server (i.e. Page 23 and Figure 2 showing such), and a PAN is again explicitly called out at page 25. By definition, a PAN uses a person's body to facilitate communications. Thus such a limitation is met by the mere presence of a PAN. Per pages 25-26, an intelligent control of medication delivery is set forth, based upon the PAN itself, by exemplary mention of the page 26 computation of a new desired dosage and the automatic administration of such, via the PAN, which per page 25, explicitly states that the patient also wears and/or uses a medication dosing device/recorder with a wireless link that transmits the dosing history. Thus a dosing device meets the claim 33 limitation of an intelligent treatment device. A cross check is performed per page 26 with the supervisory medical personnel access to the database, thus requiring at a minimum at least some sort of patient identifier to ensure the placement of data in a database. The database is consulted prior to the administration of drugs per the algorithm used to compute new dosages and administration times based upon measured variables transmitted to the database. The use of a remote database to

which the data is sent via the wireless communications link and the proposed uses of page 25 (intelligent monitors, intelligent control and dosing and compliance monitoring, battlefield soldier monitoring) all require, to at least a minimum extent, an ability to differentiate between patients to ensure proper association of the transmitted data and the database. Since all that is claimed is a "patient identifier" without any more specifics, such is anticipated by the ability of the disclosed PAN to take patient data and place such in a database, as a database involves records, and records involve, at a minimum and to the extent claimed, a differentiating patient identifier. The above dosing meets claim 35 (from the group of). A sensor is mentioned at 25 to transmit physiological data. Per the above, a patient is associated with a PAN, in that a patient is monitored and treated per the disclosed PAN. Data is recorded in the database, so that the data is associated with a record for the patient in the database, as that is how databases work. Data is obtained via the PAN. Per page 26, the sensor transmits wirelessly. Per page 24, breathing sensors will transmit a respiration rate (i.e. claim 40). Also shown is the providing of a processor for the PAN (i.e. the WISE intelligent sensor of Figure 3 with a microcontroller), with the configuring of such to facilitate communication with an intelligent health care device (i.e. the intelligent sensor or dosing device). Additionally, the treatment of a patient is set forth by the PAN and the above establishing and modifying of a dosing schedule based upon transmitted physiological data. As multiple sensors are set forth, intelligent sensors interact with intelligent treatment devices (i.e. the automatic medication dosing device) via the PAN, as each device operates on the PAN. Thus when transmitting the data, the transmitting device

has determined that the transmitted treatment data (i.e. the physiological data) is associated with the patient from which the data is obtained. When supervisory medical personnel access the database to monitor the patient measurements and dosing, a determination is made in the affirmative to correlate the treatment data to the patient identifier in order to match the transmitted data with the stored data. This also involves, to the extent claimed, the determination of appropriate treatment for the patient, as an algorithm is also used to compute new dosing schedules, hence appropriate treatment is disclosed.

As far as the transmission of a patient identifier associated with said patient in the PAN, such is an inherent feature of the disclosed system. Since the disclosed PAN uses a personal server, and the personal server includes functions such as telemedical server communications (page 23) and page 25 shows the hierarchy of the involved networks, and networks, by their nature, require identifiers such as addresses on the network, thus the personal server must have an identifier to properly operate on the network. It is to be noted, that the patient identifier is extremely broad as claimed, and the analysis above provides, via the personal server and the remote database, that at least a patient identifier is used to the extent claimed. Treatment data is retrieved via the database and then transmitted to the automatic dosing device. The telemedical server is a network device capable of storing the database, which database has to be stored in a network device as it is used by the network. Encryption of data is set forth at page 23, which would include the patient identifier. A sensor in conjunction with the processor is discussed above. The treatment device is at least a respiration rate measurement

device per Figure 2. A network is shown in Figure 1, inclusive of the PAN. A controller is seen as a telemedical server, as it controls the ultimate treatment, via the network. The telemedical server communicates via the PAN and stores the patient data in the database. Treatment is verified per patient identifier by accessing the patient's data in the database, is verified by the supervisory medical personnel accessing such which is a consistency check as well, and the treatment is carried out via acceptable protocols, or else it would not be calculated by the algorithm. Modification of the dosing schedule is set forth. Medical personnel are alerted via a systems operational check per page 26. Multiple intelligent devices are part of WISE, hence anticipation of a second treatment device is provided. Dosing history is provided by the dosing device/recorder, hence proper delivery is shown by the dosing history which is forwarded to the remote database. By definition, a PAN uses the body's electrical properties to transmit signals. As the personal server is a DSP board, it anticipates a transmitter card, as the card is not further defined. The algorithm determines a diagnosis prior to a change in the dosing schedule. This act of modifying the dosing schedule is also a determining if treatment should be delivered (i.e. claim 21). The supervisory medical personnel accessing the database to monitor the patient measurements and dosings include patient data retrieval and determination of any data conflicts, as such is the express purpose of such monitoring of measurements and dosings. Treatment is delivered via the dosing device. The dosing device is also a recorder capable of transmitting the dosing history, and since the dosing device is a WISE device, and as such is a device on the network, also includes a patient identifier to the extent claimed, as any network

device has to be identified on the network in order to work on the network. Medication dosing includes at least an administering of a shot or via an IV drip, and such is done via the patient worn medication recording/dosing device as the device administers the dosing per page 26. Treatment data is stored in the database, a network device as explained above.

Additionally (i.e. claim 28), the treatment device, such as the medication recorder/dosing device, is a network device on the WISE and must include at a minimum an identifier to work on the network, and this identifier meets the extremely broad "patient identifier", as any communication from the telemedical server, such as the data in the database or the modification of a dosing schedule, destined for the patient has to be addressed to the patient's server on the network, thus providing positive patient identification. Accordingly, treatment is delivered to the patient and carried out by operating the dosing device per the modified dosing schedule. Multiple sensors are a part of WISE.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jovanov et al. in view of Klein.

Jovanov et al. do teach explicit change in dosing, monitoring of dosing, and patient administration of dosing, but do not include a bar code and label. As discussed above, the administration of medical dosing is performed at least via a shot.

Klein teaches at Figure 2, a medication vial tag to include a bar code symbol 210 to include information about the medication and the instructions for taking such, which includes conditions pertinent to the state of the patient being monitored. Inherent to such a system is the presence of a bar code reader to read the bar code. Paragraph [0030] explicitly teaches a PAN, thereby providing motivation to combine this feature into an existing PAN.

Thus it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Jovanov et al. per the teachings of Klein in order to allow for the use of bar codes on medication vials to assist with the self administration of medications per instructions communicated via the PAN.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Russ teaches a patient monitoring area network. Brockway et al. teach an implantable sensor operable on a PAN. De La Huerga teach an identification device useable in a PAN. High Tech, High Touch teaches the basics of PAN that explicitly defines use of the body to transmit electronic data. Kong teaches the types of data stored on a HOLTER. Greene et al. is the instant application. Teller is deemed to be cumulative in its teachings compared to Jovanov et al., noting it does explicitly teach the use of an ID in each of the sensors in a PAN.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fritz M Fleming whose telephone number is 571-272-4145. The examiner can normally be reached on M-F, 0600-1500.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Gaffin can be reached on 571-272-4146. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fritz M Fleming
Primary Examiner
Art Unit 2182

fmf